UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 25, 2024

ANEBULO PHARMACEUTICALS, INC
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40388**	**85-1170950**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Anebulo Pharmaceuticals, Inc.
1017 Ranch Road 620 South, Suite 107
Lakeway, TX **78734**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (512) 598-0931

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	**ANEB**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On September 25, 2024, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter and fiscal year ended June 30, 2024 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**

99.1	Press Release dated September 25, 2024
104	Cover Page of Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANEBULO PHARMACEUTICALS, INC.

Date: September 25, 2024

By: */s/ Richard Anthony Cunningham*
Richard Anthony Cunningham
Chief Executive Officer (*Principal Executive Officer*)

Exhibit 99.1

Anebulo Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2024 Financial Results and Recent Updates

AUSTIN, Texas (September 25, 2024) – Anebulo Pharmaceuticals, Inc. (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabis-induced toxic effects (the "Company" or "Anebulo"), today announced financial results for the three and twelve months ended June 30, 2024, and recent updates.

Fourth Quarter Fiscal Year 2024 and Subsequent Highlights:

- Anebulo announced it has been awarded the first tranche of a two year cooperative grant of up to approximately $1.9 million from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH")
- With the support of NIDA, Anebulo aims to complete IND-enabling activities and the scale up of its intravenous ("IV") formulation of selonabant around calendar year end 2024 as it prepares for clinical studies and the Company expects to enroll the first healthy adult volunteer in the first half of calendar 2025
- Anebulo prioritizes development of selonabant IV formulation for unintentional cannabis poisoning in children in response to the growing medical need and impending change in Drug Enforcement Agency scheduling of marijuana from a Schedule I to a Schedule III controlled substance supported by the United States Department of Justice

"The recently awarded grant from NIDA further enables our efforts to provide a rapid and clinically impactful emergency treatment for acute cannabis-induced toxicities, including cannabis-induced Central Nervous System ("CNS") depression in children," commented Richie Cunningham, Chief Executive Officer of Anebulo.

"We believe this important grant from NIDA recognizes the progress we have already made with the successful Phase 2 proof of concept study of oral selonabant and provides further momentum for advancing the intravenous formulation towards clinical testing. We also believe this awarded grant further validates the significant and growing unmet medical need for an emergency antidote to cannabis toxicity. In particular, acute cannabis exposure in children is a serious and potentially life-threatening condition that can result in CNS depression, respiratory depression, coma, and in rare cases death. Research has shown that children are much more sensitive to the toxic effects of cannabis, due in part to age-related differences in the abundance of cannabis receptors in their brains. As a direct consequence, pediatric cannabis ingestion can result in much more serious outcomes than in adults, and a much greater risk of hospitalization and admission to intensive care. If approved, we believe selonabant has the potential to offer a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of accidental cannabis ingestion in children."

Financial Results for the three months ended June 30, 2024

- Operating expenses in the fourth quarter of fiscal 2024 were $1.3 million compared with $2.5 million in the same period in fiscal 2023.
- Net loss in the fourth quarter of fiscal 2024 was $1.3 million, or $(0.05) per share, compared with a net loss of $2.5 million, or $(0.10) per share, in the fourth quarter of fiscal 2023. Cash and cash equivalents were $3.1 million as of June 30, 2024.
- The Company has access to an additional $10 million in cash through the Loan and Security Agreement executed on November 13, 2023.

Financial Results for the twelve months ended June 30, 2024

- Operating expenses in fiscal year 2024 were $8.3 million compared with $11.8 million in the same period in fiscal 2023. Research and Development expenses decreased approximately $2.1 million from the prior year, primarily due to the completion of the Company's Phase 2 proof of concept clinical trial for acute cannabinoid intoxication ("ACI") during the first half of the fiscal year ended June 30, 2024, and prioritizing the advancement of a selonabant IV formulation, which resulted in a reduction in activities related to pre-clinical, clinical studies, and direct third-party costs. General and Administrative expenses decreased $1.4 million from the prior period, primarily due to an overall reduction in compensation and related benefits, including stock-based compensation, professional and consultant fees, and a decrease in directors' and officer's insurance premiums.
- Net loss in fiscal year 2024 was $8.2 million, or $(0.32) per share, compared with a net loss of $11.7 million, or $(0.47) per share, in fiscal year 2023. The decrease in the net loss and resulting net loss per share was the result of decreased operating expenses as discussed above.

About Selonabant (ANEB-001)

The Company's lead product candidate is selonabant (ANEB-001), a potent, small molecule antagonist of the cannabinoid receptor type-1 ("CB1"), under development to address the unmet medical need for a specific antidote for cannabis toxicity, including ACI and unintentional cannabis poisoning. Selonabant is an orally bioavailable, readily absorbed treatment candidate that the Company anticipates will rapidly reverse key symptoms of cannabis toxicity. Selonabant is also under development as an IV treatment for unintentional cannabis poisoning. Selonabant is protected by two issued patents covering various methods of use of the compound and composition of matter of the crystalline form of selonabant. Anebulo also has multiple pending applications covering various methods of use of the compound and delivery systems. An observational study in patients presenting to Emergency Departments with cannabis toxicity is currently ongoing. The study will determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected subjective assessments.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and unintentional cannabis intoxication. Its lead product candidate, selonabant, has completed dosing in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) evaluating its utility in blocking and reversing the negative effects of acute cannabinoid intoxication. Rather than proceeding directly with the Phase 3 studies of oral selonabant in adults with ACI, the Company is prioritizing the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with unintentional cannabis

poisoning, which it believes offers the potential for a faster timeline to approval relative to the adult oral product. Anebulo is currently scaling up the intravenous formulation for initial clinical safety studies. Selonabant is a competitive antagonist at the human CB1. For further information about Anebulo, please visit www.anebulo.com.

Forward-Looking Statements

Statements contained in this press release that are not statements of historical fact are forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these forward-looking statements can be identified by words such as "anticipate," "designed," "expect," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: completion of IND-enabling activities and the scale up of Anebulo's intravenous formulation of selonabant around year end 2024 as Anebulo prepares for clinical studies; enrollment of the first healthy adult volunteer in the first half of 2025; the decision by the United States Department of Justice to support the change in Drug Enforcement Agency scheduling of marijuana from a schedule I to a schedule III controlled substance; the potential of selonabant to offer a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of accidental cannabis ingestion in children; providing a rapid and clinically impactful emergency treatment for acute cannabis-induced toxicities, including cannabis-induced CNS depression in children; the NIDA grant providing further momentum for advancing the intravenous formulation of selonabant towards clinical testing and validating the significant and growing unmet medical need for an emergency antidote to cannabis toxicity. You are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the Company's ability to pursue its regulatory strategy including completion of IND enabling activities and scale up of the intravenous formulation of selonabant around year end 2024 and enrolling the first healthy adult volunteer in the first half of 2025, its ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, the Company's ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to the ability to promote or commercialize product candidates for specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of Anebulo's products, the Company's ability to maintain its license agreements, the continued maintenance and growth of its patent estate and the Company's ability to retain its key employees or maintain its Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statements included in the Company's Annual Report on Form 10-K for the year ended June 30, 2024, and its subsequent filings with the SEC, including subsequent periodic reports on Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. All forward-looking statements made in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Except as required by law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect new information, future events, changed conditions or otherwise after the date of this press release.

CONTACTS:

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Daniel George
Part time Chief Financial Officer
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Condensed Balance Sheets

	June 30,	
	2024	**2023**
Cash and cash equivalents	$ 3,094,200	$ 11,247,403
Total assets	4,073,114	11,670,151
Total liabilities	260,583	1,068,801
Total stockholders' equity	3,812,531	10,601,350

Condensed Statements of Operations

	Three months ended June 30,		Year ended June 30,	
	2024	**2023**	**2024**	**2023**
Research and development	$ 467,706	$ 1,417,159	$ 3,548,937	$ 5,600,197
General and administrative	872,661	1,077,230	4,759,818	6,183,402
Total operating expenses	1,340,367	2,494,389	8,308,755	11,783,599
Loss from operations	(1,340,367)	(2,494,389)	(8,308,755)	(11,783,599)
Other (income) expenses:				
Interest expense	59,696	-	151,230	-
Interest income	(50,218)	(6)	(249,022)	(92,407)
Other	124	1,197	(9,260)	41,146
Total other (income) expenses, net	9,602	1,191	(107,052)	(51,261)
Net loss	$ (1,349,969)	$ (2,495,580)	$ (8,201,703)	$ (11,732,338)
Weighted average common shares outstanding, basic and diluted	25,933,217	25,633,217	25,822,258	25,074,481
Net loss per share, basic and diluted	$ (0.05)	$ (0.10)	$ (0.32)	$ (0.47)